

Management Plan 2024

Health Emergency Preparedness and Response Authority (HERA)

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Introduction

The **Health Emergency Preparedness and Response Authority (HERA)** was established on 16 September 2021 "to strengthen Europe's ability to prevent, detect, and rapidly respond to cross-border health emergencies, by ensuring the development, manufacturing, procurement, and equitable distribution of key medical countermeasures (MCMs) (¹)".

The core mission of HERA is to:

| Strengthen health security coordination within the Union during preparedness and crisis response times, and bringing together the Member States, the industry and the relevant stakeholders in a common effort |
|--|
| Address vulnerabilities and strategic dependencies within the Union related to the development, production, procurement, stockpiling and distribution of medical countermeasures |
| Contribute to reinforcing the global health emergency preparedness and response architecture |

The establishment of HERA was a direct response to the COVID-19 crisis, to ensure that **Europe is better prepared and faster to react in the face of future health crises.** Throughout 2024, HERA will continue its core mission and **ensure access to and availability of life-saving medical countermeasures** for European citizens. It will continue to follow its end-to-end approach, from the identification of threats to the equitable distribution of medical counter measures to citizens and also support the work on **security of access** for critical medicines.



Investing in preparedness is essential to mitigate the risks of future health threats. In 2022, HERA produced a list of three threat categories, namely pathogens with high pandemic potential, Chemical, Biological, Radiological and Nuclear (CBRN) threats and Antimicrobial resistance (AMR) (²). In 2023, additional considerations led HERA to update its list of priority

threats, and to address more prominently climate-sensitive threats, notably vector-borne diseases, as well as threats associated with emerging technologies. These threat categories will guide all HERA's activities throughout 2024, from intelligence gathering to stockpiling, as described in HERA work plans.

(1) C(2021) 6712 final

⁽²⁾ https://ec.europa.eu/commission/presscorner/detail/en/IP_22_4474

HERA's work on threat assessments and intelligence gathering lays the foundations for the implementation of all its other tasks and is intended to complement national policies and provide support to Member States' actions.

In 2024, HERA will develop a **global wastewater sentinel system**, bringing together global airports across the enhance surveillance and pick up health threats across the globe. IT will continue the development of its IT system Athina, thereby ensuring fast and rapid access to global data, enhancing its speed of response in case of signals.

In line with its pipeline approach, HERA will continue to support **research and development** of effective, safe and affordable medical countermeasures relevant for the cross-border health threats it has prioritised. Working together with global actors such as BARDA (³) and CEPI (⁴), HERA will establish a vaccine library, fund the development innovative diagnostic devices and establish a **European clinical trial** system. HERA will also continue to financially support European based Small and Medium Sized enterprises developing innovative medical counter measures.

In 2024, HERA will continue to procure essential **vaccines and therapeutics** with and on behalf of Member States, in particular under the Joint Procurement agreement, and invest in **ever warm production facilities** and establish a **European stockpiling strategy**.

HERA will also focus on addressing the issue of **critical shortages of medicines** by implementing a substantial number of measures to mitigate those shortages in the immediate and short-to-mid-term, including the setting up of a **Strategic Alliance for critical medicines**. HERA will also launch the work on structural measures for the mid- and long-term by carrying out **vulnerability assessments of supply chains**, investing in **innovative and green production methods** and by establishing strategic partnerships with third countries.

As regards **crisis management**, the **Council Regulation** (⁵) **on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level (EFR)** provides the framework for HERA to shift into **crisis mode** and enables the Union to take necessary measures for sufficient and timely availability and supply of crisis-relevant medical countermeasures in case of public health emergencies. In terms of emergency readiness, HERA is developing **response blueprints to stress-test the emergency response protocol**. After an internal exercise in 2023, exercises with stakeholders will be held in 2024.

In accordance with Article 8 of Commission Decision C(2021) 6712 and Article 33 of the Serious Cross-Border Threats to Health Regulation (⁶), in 2024, HERA will be supporting the Secretariat-General with the **in-depth review of implementation of the operations of**

^{(&}lt;sup>3</sup>) Biomedical Advanced Research and Development Authority

^{(&}lt;sup>4</sup>) Coalition for Epidemic Preparedness Innovation

^{(&}lt;sup>5</sup>) Council Regulation (EU) 2022/2372 of 24 October 2022

^{(&}lt;sup>6</sup>) Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23.11.2022 on serious crossborder threats to health and repealing Decision No 1082/2013/EU, OJ L 314, 6.12.2022, p. 26.

HERA, including its structure and governance. The review shall address in particular any need to modify HERA's mandate and will provide an assessment of the need to establish HERA as a distinct entity.

Part 1 of this management plan outlines the main priorities and outputs of HERA for 2024. These have been constructed in order to reflect HERA's main objectives and activities as described above and as set out by the Commission via the Communication "Introducing HERA, the European Health Emergency preparedness and Response Authority, the next step towards completing the European Health Union", and the HERA Work Plan for 2024.

Part 2 of this management plan describes HERA's main outputs for 2024 that serve to set up and complete its administration for 2024, with a view to ensure efficiency across human resources, finances, digital data management, greening and fraud risk management.

PART 1. Delivering on the Commission's priorities: main outputs for 2024

General Objective 4: Promoting our European way of life.

Specific objective 1: Preparedness for health emergencies

Future serious cross-border threats to health (⁷) are likely to arise: the outbreaks of infectious diseases have been occurring with increasing frequency, driven by factors such as global population growth, climate change and pressures on land use, food production and animal health. The intentional releases of biological or chemical agents also remain a persistent threat with a potential for significant impact. To address these risks, HERA intends to focus on activities to operationalise the five preparedness tasks outlined in the Communication introducing HERA, cooperating with Member States and relevant stakeholders via the established **governance and coordination structures** such as the HERA Board and the HERA Advisory Forum.

Threat assessments and intelligence gathering. The availability of relevant and highquality data, evaluation of this data as well as that of potential threats and their impacts is essential in order to define preparedness strategies for critical medical countermeasures. In 2024, HERA will continue monitoring health threats and keep the list of main priorities up to date, building on the categories already identified, namely pathogens with high pandemic potential; CBRN threats originating from accidental or deliberate release; antimicrobial resistance, environmental threats due to climate change and threats associated with emerging technologies.

This threat prioritisation exercise has been complemented by the development of lists of critical medical countermeasures relevant for crisis preparedness and response, and the assessment of potential gaps in terms of the availability and accessibility, including research and development needs. In 2024, HERA will further refine the identification of threats and their analysis, in close cooperation with the European Centre of Disease and Control, as well as the mapping and assessment of availability and accessibility to medical countermeasures. These will enforce the preparedness and response to cross-border health threats in terms of medical countermeasures and will carry out prioritisation of MCM for monitoring of supply chains and support to research and development.

In 2024, HERA will start developing a comprehensive intelligence system for early threat identification and effective response coordination: ATHINA, the Advanced Technology for Health Intelligence and Action IT system, and will deliver already the first modules for its operation. Additional assessment of business needs will also be carried out in 2024 which

^{(&}lt;sup>7</sup>) This includes threats of chemical, biological, radiological, nuclear or environmental origin, as well as threats of unknown origin – whether of natural or deliberate origin.

will include complementarity and interoperability with existing platforms, like the European Shortages Monitoring Platform.

In 2024, HERA will strengthen sequencing capacities and will establish new activities on wastewater surveillance, such as a global consortium for wastewater surveillance for public health, covering more than 20 international airports. In particular, HERA will further strengthen wastewater monitoring capacities in the EU through knowledge exchange and sharing of best practices between Member States' authorities and will set up a testing of a number of hubs in the EU and in Africa. This action will inform wastewater surveillance strategies, technical procedures, and governance framework. Further, HERA will continue to follow the implementation of the action CP-g-22-01.04 initiated under EU4Health 2022 providing direct grants to Member States' authorities to enhance whole genome sequencing (WGS) and/or reverse transcription polymerase chain reaction (RT-PCR) national infrastructures and capacities to respond to the COVID-19 pandemic and future health threats. HERA will strengthen its collaboration with Africa CDC (⁸) to reinforce sequencing capacities and will identify areas for further collaboration in the field of intelligence gathering and access to medical countermeasures. In the field of wastewater surveillance, HERA will strengthen collaboration with WHO (⁹) and UNEP (¹⁰) to build capacities and ensure timely data exchange.

In 2024, HERA will continue to support, in collaboration with the World Health Organization and the Joint Research Centre (JRC), the technological development of the EIOS Platform (Epidemic Intelligence from open source) and contribute to its governance. This financial and operational support will strengthen the features of this platform to gather intelligence from open sources on medical countermeasures.

HERA will continue to work with DURABLE, a network of public health and research laboratories in Europe coordinated by Institute Pasteur and Erasmus Medical Centre, that has been set-up to perform research and MCM development in preparedness and response phases.

Promotion of advanced R&D of medical countermeasures and related technologies

In 2024, HERA will reinforce its horizon scanning and foresight capacities to proactively identify emerging innovations and technologies within the MCMs field. Building on the preparatory work conducted in the mapping and networking exercise of 2023, HERA will present a vaccine strategy in Q4 2024.

Through EU4Health, HERA will create the **European Vaccine Development Hub** with a view to expedite the development, production, and distribution of vaccines fostering collaboration and innovation. Based on the list of critical MCMs established in 2023 in collaboration with Member States, HERA will continue to support the development and access to a wide range

^{(&}lt;sup>8</sup>) Africa Centre for Disease Control and Prevention

^{(&}lt;sup>9</sup>) World Health Organisation

^{(&}lt;sup>10</sup>) United Nations Environment Programme

of MCMs necessary to improve preparedness and response to serious cross-border health threats, including by supporting late-stage clinical trials, clinical investigations, performance evaluation or similar studies.

In addition, HERA will contribute to the broader goal of achieving effective pandemic preparedness by supporting development of diagnostic tests and access to the right diagnostic solutions in the right settings to enable rapid detection of pandemic-prone pathogens and swift response to outbreaks. For this, HERA will work with, and support FIND, the WHO Collaborating Centre implementing the 100-day mission in the field of diagnostics.

HERA will also foster innovation in the field of personal protective equipment. The Covid-19 pandemic showcased the shortcomings of existing masks and respirators, which do not offer adequate protection or comfortable multi-hour use. An EU4Health action will address these issues, ensuring the development and uptake of improved respiratory protection.

One of the key lessons learned from the COVID-19 pandemic was the lack of a coordinated clinical trial infrastructure across the Union that could be pivoted in the case of emergency. To address this gap, HERA will create, in cooperation with DG RTD and EMA (¹¹), a coordination mechanism at the EU level that aligns funding strategies, prepares for a swift and coordinated clinical trial response in the EU during a health emergency, and streamlines the identification and prioritization of pipeline products and clinical trials.

Through Horizon Europe, HERA will support basic research aimed at increasing knowledge on viruses with epidemic potential and in particular a better understanding of pathogen-host interactions for the development of vaccines and inhibitors for the prevention of viral infection and transmission. HERA will also invest in multi-country adaptive platform trials for pandemic preparedness able to rapidly pivot to the assessment of vaccines and therapeutics for infectious diseases in the case of epidemic or pandemic health threats.

HERA will continue to be involved in the preparatory work for the creation of the Horizon Europe European Partnership on Pandemic Preparedness, which should enable Member States, Associated Countries and the Commission to rapidly and jointly support transnational research and innovation in pandemic preparedness, as well as an ever-warm clinical trial site network in the EU.

Close coordination will continue with the ongoing Innovative Health Initiative Joint Undertaking (IHI-JU) and the Global Health European and Developing Countries Clinical Trials Partnership 3 Joint Undertaking (GH-EDCTP3 JU).

For AMR, HERA will continue promoting the development and availability of relevant medical countermeasures, including old and new antimicrobials, rapid diagnostics, and vaccine against resistant pathogens. In 2024, building on the studies on 'bringing more AMR MCM on

^{(&}lt;sup>11</sup>) European Medicines Agency

the market (¹²)' and on 'stockpiling antimicrobials and Active Pharmaceutical Ingredients (¹³)', HERA will continue supporting the development, availability and access to preventive, diagnostic and therapeutic MCM for AMR.

On the side of pull incentives, HERA will continue exploring with Member States the implementation of procurement-based pull incentives, in articulation with other types of pull incentives proposed by the Commission. HERA will notably focus on the implementation of EU multi-country revenue guarantee to improve access to new antibiotics, with the support of service contracts to be passed under EU4Health action CP-p-23-16 Support innovation and access to antimicrobials.

On the side of push incentives, HERA will continue to contribute to clinical development of AMR MCM by providing a financial support to international organisations, especially the Global Antibiotic Research and Development Partnership (GARDP), a non-profit organisation that develops new treatments for drug-resistant infections that pose the greatest threat to health. In addition, HERA will collaborate with DG RTD in the work of the Horizon Europe co-fund European Partnership 'One Health Anti-Microbial Resistance', to be launched in 2025, which should allow coordinating, aligning of activities and funding among countries in the EU and beyond, as well as facilitating national coherence between different services/ministries with responsibility for the various aspects of AMR and sectors involved.

As regards the availability of older broad-spectrum antibiotics, in 2024 HERA will reflect on the joint procurement model for these products that would incentivise additional manufacturing capacities and complement the national procurement initiatives.

Ensuring access to medical countermeasures and boosting the Union's open strategic autonomy

Shortages of medical countermeasures can be a result of a lack of manufacturing and supply capacities due to surge of demand, vulnerabilities in global supply chains and dependencies on third countries. In 2024 HERA will operationalise a **Strategic Alliance for Critical Medicines** with an overall objective to boost EU capabilities by closer coordination between industry, Member States, the Commission, EU Agencies and other relevant stakeholders. The work will entail the **identification of bottlenecks**, **mapping and monitoring of supply chains and manufacturing capacities**, as well as the **creation of industrial partnerships and cooperation structures with Member States**, **research and civil society**.

One of the key lessons learned from the COVID-19 pandemic was that while effective vaccines could be quickly developed and authorised, manufacturing capacities were insufficient in the early stages to rapidly meet demand both at Union and global levels. In

^{(&}lt;sup>12</sup>) https://op.europa.eu/en/publication-detail/-/publication/51b2c82c-c21b-11ed-8912-01aa75ed71a1/language-en/format-PDF/source-282347876

^{(&}lt;sup>13</sup>) https://health.ec.europa.eu/latest-updates/hera-commissioned-feasibility-study-stockpilingantimicrobials-against-amr-published-2023-02-02_en

2024, HERA will continue to monitor the implementation of the **EU FAB** (¹⁴) and secure early availability of vaccines in case of a future public health emergency. EU FAB will complement capacity reserved by Member States at national level. In 2024, HERA will expand the EU FAB framework beyond vaccines to conclude additional capacity reservation contracts for the development of and access to innovative technologies and critical medicines, including antibiotics.

In 2024 HERA, together with DG GROW, will finalise and apply the methodology to assess the vulnerability of supply chains of selected critical medicines, as resulting from the EMA/HMA (¹⁵) exercise. HERA will also work on an EU mechanism of demand signalling to better forecast the demand for the Medicinal countermeasures.

HERA will also develop a MCMs supply chain risk management framework to devise new supply chain technologies for improving the visibility, agility, and resilience of end-to-end MCM supply chain networks and to transform gained knowledge and information (data) to actionable insights, through HERA's IT platform. Through the MCMs supply chain risk management framework, HERA will map and assess supply chain network criticalities of a targeted list of critical medical countermeasures through exchange of qualitative and quantitative data with final product manufacturers and Active Pharmaceutical Ingredients (APIs), intermediate ingredients and raw material suppliers, including within the Joint Industrial Cooperation Forum (JICF) – brings together the Commission, Member States and industry- and through the monitoring scheme for trade flows of critical components for vaccines and therapeutics (¹⁶). HERA will establish a match making platform to support the MCM developers and producers facing supply chain issues and support fostering of networking and business relationships through HERA Industry Days.

To further address some market challenges and support innovative development of medical countermeasures, HERA will continue to follow the implementation of HERA Invest by bringing an additional EUR 10 million top-up to the guarantee. In 2024, the European Investment Bank is expected to implement the first loans to selected small and medium enterprises in the EU. Furthermore, HERA will continue to follow the preparatory work by Member States for potential **Important Projects of Common European Interest on Health (IPCEI)** which encourage cross-border innovations in areas such as critical medicines, AMR and emerging health threats.

HERA will also launch the work on structural measures for the mid- and long-term, in particular in cooperation with the industry and stakeholders through a Strategic Alliance for Critical Medicines and strategic partnerships with third countries.

^{(&}lt;sup>14</sup>) Network of Ever-warm Production Capacities for Vaccines and Therapeutics manufacturing

^{(&}lt;sup>15</sup>) Heads of Medicines Agencies

^{(&}lt;sup>16</sup>) JICF discussions will also explore options to boost the EU's strategic autonomy for the production of critical MCMs.

In cooperation with DG BUDG, HERA will promote the goal of the proposed Strategic Technologies for Europe Platform (STEP) to support investments in companies that contribute to preserving a European edge on critical biotechnologies. For example, the creation of a European hub for vaccine development, and the top-up to HERA Invest support European innovation in strategic technologies. Reaping the full benefits of biotechnology can help the EU economy grow in respect of priorities such as sustainable development, public health, and environmental protection.

Strengthened knowledge and skills. In 2024, HERA will continue to organise exercises and the training sessions on stockpiling and procurement, based on the success of 2023 events and based on the result of the training gap analysis to be carried out in 2024. This gap analysis will also contribute to the EU Skills Agenda by supporting the identification of skills and training needs related to the entire development, production and distribution cycle of medical countermeasures. As in 2023, HERA will continue dialogue with Civil Society and Joint Industrial Cooperation Fora on skills identification and pooling of training offer.

Governance and coordination. HERA's work in health preparedness and emergency response to health emergencies involving medical countermeasures has an impact on several sectors, such as health, research, innovation and industry. Based on the governance and coordination mechanisms put in place in 2022 with Member States, other Commission Services and Agencies as well as specific groups of stakeholders HERA in 2024 will continue building knowledge on existing structures with relevant mandates, tasks and functions to HERA within **Member States** and **globally** (e.g. entities responsible for carrying out tasks related to the availability and accessibility of relevant medical countermeasures in case of a health emergency). This knowledge will support the Commission to establish a pan-European network as well as build effective cooperation internationally. In addition, the continuous engagement and interaction with the HERA Advisory Forum as well with the Joint Industrial Cooperation Forum and the Civil Society Forum has enabled the establishment of an effective communication channel with crucial stakeholders. HERA has built close links with different Commission services. A HERA Inter-service steering group (HERA ISSG) has been set-up, which is systematically consulted.

HERA has examined a possible contribution to the objective of simplification and rationalisation of reporting obligations. Since there are no legally binding acts under the responsibility of HERA that provide for reporting obligations creating burden on businesses and national administration, HERA will not contribute to this objective this year. However, should binding legal acts introduce reporting obligations, especially following the activation of measures related to public health emergencies outlined in Regulation (EU) 2022/2372, HERA intends to minimize such obligations to only essential requirements for obtaining meaningful information from businesses and public administration. HERA has formulated a plan to assess the proportionality and the necessity of any requests, in case the relevant public health emergency measures are activated, concerning the production, availability and supply of crisis-relevant medical countermeasures production and production facilities, and, as appropriate, of crisis-relevant raw materials, consumables, medical devices,

equipment and infrastructure, and including measures aimed at increasing their production in the Union.

Specific objective 2: Crisis response readiness for health emergencies

Crisis mode – response protocol. In 2024, HERA will operationalise its emergency response protocol, which facilitates and supports HERA crisis response regardless of whether health emergency is declared at EU level.

HERA will continue carrying out a preparatory work for the implementation of Council Regulation (EU) 2022/2372 on a framework of measures for ensuring the supply of crisisrelevant medical countermeasures in the event of a public health emergency at Union level, **in order to prepare for** a possible declaration of health emergency (¹⁷) at Union level, and to be able to adopt swiftly the necessary implementing measures. More specifically, HERA will continue working for the establishment of procedures for the **activation, prolongation and expiration of the framework.** In terms of emergency readiness, HERA will pursue the development of several response blueprints to **stress-test** the **emergency response protocol**. This will involve identifying the response measures to be taken according to the HERA priority threats, conducting exercises, including with stakeholders. HERA will also create other training and exercise programmes to strengthen knowledge and Commission activities.

Response to outbreaks. In 2024, HERA plans to keep and improve its ability to help EU countries with outbreaks of emerging or existing diseases. HERA will build on the lessons learned from the MPOX outbreak in 2023 and continue to follow up the implementation of the actions related to the detection of cross border health threats extending the activities, such as whole genome sequencing, testing capacity and wastewater monitoring. These intelligence gathering activities on potential threats will contribute to these readiness efforts. Response measures will build include the activation of EU FAB, the deployment of stocks constituted under rescEU or the deployment of vaccines and therapeutics purchased via HERA's own procurement tools, such as for instance for avian influenza.

Provision of medical countermeasures in times of crisis. Immediate access to needed medical countermeasures is essential in order to respond to health emergencies. Ensuring such access can be enabled by rapid public procurements and distribution of stockpiles. Through EU4Health, HERA will ensure rapid mobilisation of funds in case of emergency and will support the provision of critical medicines in shortages. In addition, stockpiles of CBRN and other medical countermeasures of a value of EUR 1.2 billion have now been constituted under rescEU. In 2024, HERA will collaborate with rescEU to operationalise the management and deployment of the stocks in the most efficient way. In 2024, HERA will continue coordinating the work on the development of a **common strategic approach to medicines**

⁽¹⁷⁾ Regulation (EU) 2022/2371 of the European Parliament and the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU

stockpiling. To support the implementation of such a strategic approach, HERA will launch a Joint Action on stockpiling in early 2024.

COVID-19 vaccines/therapeutics and response to variants. In 2024, HERA will focus on the implementation of the ongoing contracts, as well as, assisting Member States interested in joint procurement of COVID-19 available vaccines. HERA will also continue supporting the development, manufacturing, and availability of improved vaccines against COVID-19. That strategy will incorporate a longer-term view, beyond the immediate threat of COVID-19 vaccines, to develop the EU's capacity to manage emerging health threats.

Since the outbreak of COVID-19, several SARS-CoV-2 variants of concern have been detected, reported and monitored. These variants can pose a significant challenge to overcoming COVID-19, notably as they can undermine current vaccine strategies.

These activities will also include the characterisation of SARS-CoV-2 variants and other threats in case urgent support is needed, through DURABLE (a European network of laboratories with global reach) that can provide rapid insights and develop targeted medical countermeasures to fight against those threats. In addition to this, HERA will continue to consult the European expert group on SARS CoV-2 variants to advise on the need to develop new or adapted vaccines in view of new emerging variants. In line with the potential risks that new variants pose to the effectiveness of existing COVID-19 vaccines, HERA will continue to closely liaise with vaccine producers who are constantly analysing testing effectiveness of their vaccines against variants, working together with DG SANTE and EMA (¹⁸) with regard to regulatory aspects related to the authorisation of these vaccines. Should there be a need for further adaptation to new variants of concern in the course of 2024 HERA will ensure the respective follow up.

Response to Russia's invasion of Ukraine. Since the start of Russia's invasion of Ukraine, HERA has worked closely together with DG ECHO's Emergency Response Coordination Centre to help channel medical countermeasures to Ukraine and neighbouring countries in need. HERA worked also particularly close together with EMA to monitor whether the invasion had an impact on the availability of medicinal products in Europe. In 2024, and for as long as needed, HERA will continue this work to support Ukraine with the necessary medical countermeasures. Particular attention will be put to the health needs which as not necessarily covered by the humanitarian aid in war zone, such as the provision of paediatric vaccines, in order to avoid a long-term deterioration of the health of the population. Coordination with international actors like WHO and UNICEF will be of paramount importance in that regard.

Communication. As a new entity, HERA must continue developing a strong identity and brand. In particular in crisis time, HERA will need to ensure the visibility of its response. HERA will place communication side by side to policy, to ensure that the relevant information is well communicated and widely known through multiple channels including press materials via the Commission's Spokesperson's Service, regular updates to HERA's website,

^{(&}lt;sup>18</sup>) European Medicines Agency

Commission social media channels (notably, on X and LinkedIn) and a newsletter foreseen throughout 2024.

HERA Review: This review fulfils the obligation under article 8 of the Commission Decision C(2021)6712 of 16 September establishing HERA. The article prescribes an in-depth review of the implementation of the operations of HERA before 2025, including its structure and governance, addressing in particular any need to modify the mandate of HERA and the financial implications of any such modification. The main objective of the report on the review of the implementation of the operations of HERA is to assess the extent to which HERA's mandate and tools (legal basis, structure, governance, funding) has allowed it to effectively and efficiently contribute to the political objective of strengthening the EU's health emergency preparedness and response, and fulfil the tasks as laid down in Commission Decision C(2021) 6712. The report will also look at the complementarity with work carried out by other EU bodies. This analysis will support the assessment of the need to establish HERA as a distinct entity, considering relevant agencies or authorities active in the field of health preparedness and response. The report will also analyse to what extent the HERA mandate fits the current health challenges and if any changes to this mandate are needed. SG is the responsible service for the publication of the report with HERA being co-responsible DG. The report will be informed by an open public consultation which was launched in "Have Your Say" portal on 27 November 2023. (19) HERA has launched a study with an external contractor to support the review. The results of this study will be published in April 2024.

Specific objective 3: International resilience and appropriate response readiness for health emergencies

The COVID-19 crisis has clearly illustrated the need to ensure equitable global access to COVID-19 vaccines, without which our ability to overcome the pandemic is severely hampered and the human costs of the pandemic will continue to rise. At the same time, COVID-19 has also clearly shown deficiencies in global preparedness, prevention and detection of health emergencies. HERA will therefore pursue several activities at an international level: collaboration with global partners to address international supply chain bottlenecks, expanding global production, reinforcing global surveillance, facilitating cooperation and support with global actors to ensure availability and accessibility for medical countermeasures for the Union and third countries, focusing in particular on Africa in collaboration with DG INTPA. Building expertise to develop local manufacturing and distribution capacities and supporting access to EU funded or EU procured medical countermeasures. In addition, HERA will continue to actively contribute to Commission's exercise of the external representation in global fora, such as G7 and G20, where such issues are also discussed. HERA will also continue to support the Commission's efforts as Union negotiator in the negotiations of the Pandemic Agreement, in particular with regard to commitments for the provision of medical countermeasures and to the inclusion of AMR and One Health provisions in the pandemic treaty. HERA will continue following closely the WHOled consultations on the interim MCM network, by participating in the technical mapping

^{(&}lt;sup>19</sup>) https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14035-Health-Emergency-Preparedness-and-Response-Authority-HERA-review_en

exercise and related discussions. HERA will also support the Commission's ambition to increasing funding for pandemic preparedness and response (PPR) globally, in particular through the Pandemic Fund.

HERA will continue to support Member States with the donation of COVID-19 vaccines to Gavi and bilaterally. In addition, HERA will continue supporting financially global, regional and national initiatives, to **ensure the availability and accessibility of medical countermeasures** and **strengthen the capacities of Low-and Middle-income Countries (LMIC) to carry out surveillance and whole genome sequencing activities.**

HERA will continue strengthening the global health emergency response architecture by collaborating with EU and international partners to develop new and implement existing working arrangements, focusing on preventing and addressing serious cross-border health threats in the area of medical countermeasures.

HERA has ongoing active collaboration with the United States, Japan, Korea, Canada, the World Health Organization, philanthropic foundations, such as the Bill & Melinda Gates foundation and the Africa Centres for Disease control and Prevention (Africa CDC). With some key partners, such as the U.S. Department of Health & Human services, the Ministry of Health and Welfare of the Republic of Korea, the Japan Agency for Medical Research and Development, or the WHO Hub for Pandemic and Epidemic Intelligence, the cooperation has been formalised through **administrative arrangements (20)**. Further cooperation arrangements are anticipated in 2024 with other key partners.

HERA will also continue to work with candidate countries, potential candidates, and neighbourhood countries.

Importantly, HERA is responsible for implementing the **joint procurement contracts for COVID-19 vaccines and therapeutics**. Participation in the Joint Procurement Agreement now totals 36 signatories, **covering around 470 million people, including all EU and EEA population and almost all Candidate and Potential Candidate Countries.**

In order to address **medicine shortages** in the EU, HERA – in collaboration with other Commission services - will establish a network of international partners and companies to boost the exchange of information on supply issues, and support Team Europe initiatives to enhance production capacity and access in low- and middle-income countries and reinforce cooperation on prevention and preparedness. HERA will also help develop strategic partnerships with third countries for production of critical medicines, reflecting both local demand and needs at the EU and global level.

^{(&}lt;sup>20</sup>) or Letter of Intent, in the case of CEPI.

PART 2. Modernising the administration: main outputs for 2024

The internal control framework (²¹) supports sound management and decision-making. It notably ensures that risks to the achievement of objectives are taken into account and reduced to acceptable levels through cost-effective controls.

HERA has established an internal control system tailored to its particular characteristics and circumstances. The effective functioning of the service's internal control system will be assessed on an ongoing basis throughout the year and be subject to a specific annual assessment covering all internal control principles.

A. Human resource management

The draft budget 2024 will bring HERA's total allocation to 104 FTEs, well below the initially estimated necessary workforce (130 FTEs). HERA needs more staff to effectively carry out its work notably in the light of the additional work stemming from the Communication on addressing critical shortages of medicines in the EU of 24 October 2023. With this communication HERA is now entrusted with several additional tasks of political importance linked to the competitiveness, strategic autonomy and the resilience of the pharma industry, beyond medical countermeasures. HERA will need reinforcement of its staff, as soon as possible in 2024, to be able to deliver on its commitments.

HERA has reached 50% of female middle management and will do its utmost to maintain • this balance in accordance with the principle of balanced first appointments at middle management level (SEC (2023) 200). HERA will continue to boost the motivation of female team leaders to apply to middle management posts via the Female Talent Development Programme. 68% of staff in HERA are women and recruitments always aim at equal competence at reaching a better gender balance. 2 senior management posts remain vacant and should be filled in 2024. In 2024, the strategic approach for HERA HR management will be to further improve organisational development aspects such as on boarding, training, knowledge and information sharing, clarity of the portfolios, jobs, objectives, internal communication. With the appointment of an equality correspondent in 2023, HERA will be better equipped in 2024 for the establishment and implementation of the internal dimension of the equality mainstreaming work plan. In 2024, HERA will for the first time have results from the staff survey which will be useful to steer the focus of HR activities on priority areas to maintain the high motivation level and staff engagement. Currently staff engagement is boosted with a lot of teamwork across units where staff can lead on specific projects of relevance to the DG. The functioning of the organisation is very flat and allows young staff to attend high level meetings and participate in important missions. In general, the level of

^{(&}lt;sup>21</sup>) <u>Communication C(2017)2373 - Revision of the Internal Control Framework</u>

autonomy and responsibility in HERA is higher than in more established DGs at all levels of the organisation. This is a strong factor of engagement.

B. Sound financial management

In 2024, HERA budget will be composed of contributions from the EU4Health and Horizon Europe programmes. The focus will be again on ensuring close contact and coordination with partner DGs to have HERA priorities met through full budget execution.

In 2024, HERA will implement a minor portion of its EU4Health budget directly with the assistance of DG SANTE for financial initiation and verification. HERA will continue to rely on DG SANTE for the set-up of cost-effective controls that give the necessary guarantees concerning the legality and regularity of the underlying HERA transactions.

For a major part of its EU4Health budget, HERA will supervise the budget implementation tasks transferred to the Health and Digital Executive Agency (HaDEA). HERA will also cooperate closely with DG RTD for the implementation of its Horizon Europe budget.

HERA has established an internal control system tailored to its characteristics and circumstances. The effective functioning of the service's internal control system will be assessed on an ongoing basis throughout the year and be subject to a specific annual assessment covering all internal control principles.

HERA Internal Control Framework (ICF) and Internal Control Monitoring Criteria (ICMC) were revised in 2023 to address IAS recommendations following a limited review on HERA's assessment of its Internal Control Framework for the 2022 AAR. HERA ICF supports sound management and decision-making, and notably ensures that risks to the achievement of objectives are considered and reduced to acceptable levels through effective and efficient controls.

HERA management is informed about budget implementation and control results to monitor budget execution indicators on a regular basis. In addition, HERA receives feedback from audits of the Commission's Internal Audit Service and the European Court of Auditors and compiles, implements and monitors the corresponding action plans.

C. Fraud risk management

Fraud risks are addressed by specific controls designed and implemented to mitigate the risks. HERA developed in 2023 its first **anti- fraud strategy** as well as an **action plan with a duration of three years.** In 2024, HERA will start implementing the actions listed in the action plan mentioned before.

The controls to prevent and detect fraud are basically the same as those intended to ensure the legality and regularity of the transactions. An assessment of the risks of fraud will be included in the annual risk management exercise. In addition, the tasks listed in the table below are especially important to HERA and will contribute to the objectives of the Commission Anti-Fraud Strategy and its revised Action plan.

The Internal Control framework was revised in 2023 and a good management and follow-up of risks will be ensured.

In 2024, HERA will pursue its commitment to ensure integrity and ethical values. In particular, HERA staff shall ensure full transparency and equal treatment regarding the relations between HERA and the vaccines and medical countermeasures producers, including the strict implementation of the Transparency Register and of the Code of Good Administrative Behaviour. HERA will further strengthen the knowledge and maintain a high level of awareness among Commission staff regarding ethics and anti-fraud matters with an increased monitoring of the attendance to the compulsory training courses on ethics good administrative behaviour and anti-fraud. The guidelines on whistleblowing are part of the online information for newcomers which is sent as part of the onboarding. HERA will also continue to actively participate in OLAF's Fraud-Prevention and Detection Network (FPDNet)

D. Digital transformation and information management

Digital transformation

In 2024, HERA will develop the foundation of an information platform, that will allow for detection, analysis and monitoring, of pertinent health threats, related to an outbreak of a specific disease and bottlenecks in supply chain of crisis-relevant Medical Counter Measures. This HERA IT platform (HERA's Advanced Technology for Health Intelligence and Action IT Platform or ATHINA) will support the HERA activities in both preparedness and crisis mode.

In line with the Commission Digital Strategic objectives, HERA has identified the following key initiatives:

Strategic Objective 1: Improving Digital Culture:

To ensure that all key users of the HERA IT platform have sufficient digital skills to be able to leverage the full functionality, training sessions will be provided for the HERA IT platform and is expected to be a key success criterion for the implementation of the platform.

In 2024, HERA will promote Cyber Security awareness and the use of Artificial Intelligence by knowledge hours and info sessions, and this in collaboration with other Commission Services. Data Protection best practices will be provided to newcomers to HERA as part of the welcome pack.

Strategic Objective 2: Digital-ready EU policymaking:

While no major IT related policy making initiatives are currently on the 2024 horizon for HERA, the planned activity in 2024 is to implement the current legislative initiatives and to provide a return on experience towards the policy teams on the ease of IT implementation of policy initiatives. HERA will involve the Digital Ready Policy Making (DRPM) team in the feedback loop of the 'return on experience towards the involved policy teams' as relevant knowledge of good practices and lessons learnt. Furthermore, HERA will engage in raising awareness around digital-ready policymaking within the DG by promoting training on digital-ready policymaking.

Strategic Objective 3: Impact on Business-driven Digital Transformation:

In 2024, as part of the analysis of future needs for the HERA IT platform, the potential to leverage Artificial Intelligence and other innovative approaches with other Commission Services across the emergency health response community at EU level and internationally, will be analysed.

In addition, HERA will use solutions on data lakes and data spaces to facilitate collection, dissemination and analysis of large data sets.

In 2024, with the implementation of the first functionalities of the HERA IT platform, HERA focuses on ensuring useful data visualisation and reporting tools as well as a thorough analysis of all the processes and exchanges between HERA and other Commission Services. This will allow to properly map the need for automation more broadly.

Furthermore, the first functionalities of the HERA IT platform will facilitate the gathering of information through a secured survey module, reducing the workload of the HERA desk officers while ensuring the secure processing of the collected data.

Strategic Objective 4: Impact on Seamless digital environment:

In 2024, during the analysis of the future additional functionalities of the HERA IT platform, HERA will apply the dual pillar approach (i.e., HERA will first try to reuse existing, ideally opensource, solutions or if appropriate go for off-the-shelf products) and continue to ensure proper analysis of all digital investments. Since HERA is a young organisation, there is no legacy tooling to be phased out.

The development of the HERA IT platform will offer a user-friendly and better access to information on HERA to internal and external stakeholders.

Strategic Objective 5: Impact on Green, secure and resilient Infrastructure:

HERA is fully focused on the use of cloud solutions where security and data protection constraints are respected.

Cybersecurity and the overall IT security are a key priority for HERA. In 2024, HERA will onboard the use of the Commission Information Technology Security Risk Management

methodology (ITSRM) for security assessment and consequence plans for the HERA IT platform. As the platform matures, audits will be enforced, and an effort will be made to improve the resilience of the platform to help mitigate against cyber-attacks.

During the development of the HERA IT platform, HERA will ensure its full compliancy with data protection rules by continuous implementation of the therein-embodied principles.

Information and IT security rules

In particular in its relations with public and private stakeholders, HERA handles sensitive nonclassified ('SNC') (and classified information ('EUCI')). In 2023, HERA established internal guidance on the handling of sensitive non-classified information, especially in relation to interactions with external public and private stakeholders. In 2024, the HERA Local Security officer will promote security awareness, manage requests for access and for security clearance (physical and personnel security), and advise the staff on the security of EU classified information including in relation to related to classified contracts (industrial security).

The following guidelines and objectives will apply for HERA:

- Secure deployment of new cloud workloads using the principles and rules on outsourcing of critical infrastructures (CIs), the European Commission Managed Landing Zone and the recommendations of the Cloud Council (such as the management of Sensitive Non-Classified data in Infrastructure-as-a-Service and Platform-as-a-Service, the secure use of Software-as-a-Service)
- Finalisation and approval of the IT security plan of the HERA IT Platform before its entry into operation, with associated implementation of all security controls foreseen in it.
- Implementation of an effective risk management methodology and toolset such as ITSRM in collaboration with and with guidance from DIGIT.
- Mandatory cybersecurity and information security training for all newcomers.
- All staff is invited by the Commission for a yearly knowledge assessment related to cybersecurity essentials and cyber hygiene, to take an online training and participate in phishing exercises.

Data, information and knowledge management

Sound document management

In 2024, HERA will continue working according to the established document management and access to documents procedures. Internal procedure on handling paper documents will be developed and implemented. Guidelines will be distributed across the DG and relevant colleagues will receive the necessary training.

Promoting knowledge sharing

Launched in 2023, HERA will continue developing and curating the content of HERA Knowledge Portal – new (SharePoint Online) site with the internal repository of high relevance documents.

Data protection

HERA remains committed to ensure full compliance with data protection rules and rigorous implementation of therein-embodied principles.

In 2024, the HERA Data Protection Coordinator (DPC) will focus on three pillars:

- Awareness raising: HERA will continue to increase awareness at all levels of HERA staff, focusing on the needs of every type of actor and on the practical implementation. This will be achieved by a variety of awareness activities, including on the most recurrent and risky activities, such as public procurement procedures, the development and application of IT tools, Data Protection Impact Assessments, meetings and events, consultations, international transfers and data subject request procedures. Awareness raising sessions will be organised for each Unit, while newcomers will be specifically given an introductory course on data protection compliance in HERA.
- **Development and update of digital solutions and systems:** HERA will continue its efforts to ensure that the design or update of (future) HERA IT systems and websites respect the principle of data protection by design and default.
- **Inventory of processing operations:** HERA will map the implementation of data protection rules and increase monitoring capabilities, in particular by promoting the use of 'unit inventories' of processing operations, including record-keeping activities.

E. Sound environmental management

HERA is still temporarily hosted in a site in Brussels, with a permanent location in Brussels expected to be decided and implemented during 2024. HERA will continue participating to central actions aiming at energy savings each time possible and will further take into account the environmental aspects of missions and meetings. A next step would be to add green provisions in contracts wherever possible. Once HERA's long-term building location has been arranged, HERA will begin its full integration into EMAS (Commission Eco-Management and Audit Scheme). In February 2023, HERA appointed an EMAS correspondent (as well as a backup). HERA EMAS Correspondent has been promoting staff awareness and participation in environmental management by conveying EMAS corporate information to HERA staff, participating in EMAS corporate events and in EMAS operation: network meetings, trainings, annual internal audits and verification exercises. Project for 2024 is to set up a local team of volunteers and organize a local EMAS action/event.

Regarding missions and business travels of staff and experts, teleworking and videoconferences have intensively been used and HERA will continue these practices throughout 2024 to further implement the Pledge for the Greening of missions and meetings signed by HERA in 2022. This supports the sustainability of conferences and events as well as intensive use of digital means for working and communication within HERA.

F. Initiatives to improve economy and efficiency of financial and non-financial activities

HERA is not yet at its full expected capacity, but for HERA to be able to deliver on its mission, much more staff would be required, between 2024 and 2027 as assessed in the context of the annual budgetary process. These scarce resources generate constant need for reinforcement of teams via internal redeployment on priority files and a project-based approach with teams across units depending on competences' needs. HERA has therefore developed a lot of activities in this format which is saving resources but also creates a lot of pressure on staff to contribute to numerous initiatives. For each vacant post, the top management analyses where are the areas that have the maximum priorities and most urgent and important deliveries to allocate the posts accordingly. The new initiatives, the outputs mentioned in the management plan and the budgetary process are part of the assessment process for the needs. Units (managers and staff) have also been consulted to give their vision of the future of the organisation and related needs in terms of staff which is part of the assessment also. Moreover, managers are in constant exchange with the HR Correspondent and the Senior management to signal their needs/difficulties. This combination of elements informs the decision on post allocation internally with the best possible prioritisation and efficiency.

ANNEX: Performance tables - main outputs for 2024

Part 1 - Delivering on the Commission's priorities

General objective: Promoting our European way of life

Specific Objective 1: Preparedness for health emergencies

Related to spending programme(s): Horizon Europe; EU4Health programme; Union Civil Protection Mechanism (rescEU)

| Main outputs in 2024: | | |
|---|--|----------------------------|
| Other important outputs | | |
| Output | Indicator | Target |
| Threat assessments and in | itelligence gathering | |
| First functionalities (survey and case management) of the HERA IT platform in production | Acceptance of the first functionalities (survey and case management) of the HERA IT platform | Q4 2024 |
| Creation of a Global Wastewater Sentinel System | Implementation | Q1 2024 |
| Support strategies, capacity and data for global wastewater and environmental surveillance | Implementation | Q1-Q2 2024 |
| Support to the Commission on intelligence gathering on priority threats and medical countermeasures | Launch | Q1-Q2 2024 |
| Promoting advanced R&D | of medical countermeasures | s and related technologies |
| Vaccine strategy | Presentation | Q4 2024 |
| Pandemic Preparedness Partnership | Establishment | Q4 2024 |
| Adaptive platform trials for pandemic preparedness | Launch | Q1 2024 |
| Host-pathogen interactions of infectious diseases with epidemic potential | Launch | Q1 2024 |
| European Innovation Council challenge on monoclonal antibodies | Launch | Q1 2024 |
| The European Vaccine development Hub | Launch | Q1-Q2 2024 |
| Call for proposals for next-generation respiratory protection | Launch | Q1-Q2 2024 |
| Call for proposals for novel antivirals | Launch | Q1-Q2 2024 |
| Call to speed up the development of, access to and/or uptake of medical countermeasures | Launch | Q2-Q3 2024 |

| Output | Indicator | Target |
|--|---|--------------------|
| Speed up the development of and access to innovative medical countermeasures including critical medicines | Launch | Q2-Q3 2024 |
| Provide financial support to GARDP for the development of antibiotics to strengthen global preparedness and response | Agreement signed | Q1-Q2 2024 |
| Provide financial support to for implementing the diagnostics component of the 100 Days Mission | Agreement signed | Q2-Q3 2024 |
| Ensuring access to MCMs a | and boosting the Union's str | ategic autonomy |
| Pilot action to support innovation to improve manufacturing technologies and processes for medical countermeasures and active pharmaceutical ingredients | Launch | Q1-Q2 2024 |
| EU FAB | Expansion of framework beyond vaccines | Q4 2024 |
| Strategic Alliance for Critical Medicines | Launch | Q1 2024 |
| HERA Invest | Implementation and development | Q2-Q3 2024 |
| Provision of medical count | ermeasures | |
| Common strategic approach to medicines stockpiling | First draft submitted to Member States | Q2 2024 |
| Study on stockpiling | First inception report | Q3 2024 |
| Provision of logistics and transport solutions for Medical Countermeasures | Activation of funding | Based on needs |
| Support to purchase, innovation, and deployment of MCMs in emergencies | Activation of funding | Based on needs |
| WHO logistic Hub Dakar | Implementation | Q2-Q3 2024 |
| EU Mechanism for demand signalling | Establishment | Q3 2024 |
| Strengthened knowledge a | Ind skills | |
| Study on training gaps | Final report | Q3 2024 |
| Dialogue with Civil Society and Joint Industrial Cooperation Forum | Number of meetings | At least 2 |
| Training related to MCM | Number of Trainings (including workshops and e-learning) | At least 3 in 2024 |
| Governance and coordinat | ion | |
| Study on mapping structures with relevant mandates, tasks and functions to HERA within Member States and globally | Final report | Q2 2024 |

General objective: Promoting our European way of life

Specific Objective 2: Crisis Response readiness for health emergencies Related to spending programme(s): Emergency Support Instrument, EU4Health

| Main outputs in 2024: | | |
|--|----------------------------------|-----------------|
| New policy initiatives | | |
| Output | Indicator | Target |
| Staff working document to accompany the communication from the Commission to the EP and the Council on the review of the implementation of the operations of the Health Emergency Preparedness and Response Authority (HERA) | Publication | Q2 2024 |
| External communication a | ctions | |
| Output | Indicator | Target |
| Launch of revamped HERA website in Q1 2024 to increase brand awareness | Number of visits | 50% increase |
| Launch of HERA quarterly newsletter in Q1 2024 to disseminate relevant and up to date information to stakeholders | Number of subscribers | 500 subscribers |
| Other important outputs | | |
| Output | Indicator | Target |
| Study supporting the review of HERA with regard to its operations, structure and governance | Final report | Q2 2024 |
| Conduct of simulation exercises to test preparedness, readiness and response plans. | Number of exercises | 2 |
| Joint Action on stockpiling | Number of Member States involved | At least 4 |
| Study on potential Critical Medicine Act | Final report | Q3/Q4 2024 |

General objective: Promoting our European way of life

Specific Objective 3: International resilience and response readiness for health emergencies

Related to spending programme(s): Emergency Support Instrument, EU4Health

Main outputs in 2024:

Other important outputs

| Other Important outputs | | |
|--|--|--|
| Output | Indicator | Target |
| Implementing existing administrative and working arrangements with international stakeholders | Identification of concrete collaborative projects | Monitor every six months following signature |
| Structured collaboration with international stakeholders on health emergency preparedness and response and the production of critical medicines, including through the signature of administrative arrangements | Signature of the arrangements and establishment of relationships | Throughout the year |
| Network of international partners and companies to boost the exchange of information on critical medicines' supply issues | Launch | Q2 2024 |

Part 2 - Modernising the administration

A.Human resource management

Objective: HERA employs a competent and engaged workforce and contributes to gender equality at all levels of management to effectively deliver on the Commission's priorities and core business.

Main outputs in 2024:

| Output | Indicator | Target |
|--|-------------------------------|--|
| Boost motivation of Female AD Team leaders to apply for management post by providing the appropriate training to relevant candidates. | 50% of female middle managers | 2 or more As Hera had no 2023-2024 gender target, respect the principal of making balanced 1 st appointments in MM positions. |

B.Sound financial management

Objective: The authorising officer by delegation has reasonable assurance that resources have been used in accordance with the principles of sound financial management and that cost-effective controls are in place which give the necessary guarantees concerning the legality and regularity of underlying transactions.

| Main outputs in 2024: | | |
|---------------------------------------|------------------------------------|--|
| Output | Indicator | Target |
| Effective controls: Legal and regular | Estimated risk at payment | N/A |
| transactions | Estimated risk at closure | N/A |
| Efficient controls | Budget execution | Remains at least 95% of payment appropriations |
| Economy of controls | Overall estimated cost of controls | N/A |

C. Fraud risk management

Objective: The risk of fraud is minimised through the application of effective anti-fraud measures and the implementation of the Commission Anti-Fraud Strategy (CAFS) (²²) aimed at the prevention, detection and correction (²³) of fraud.

| Mat | nite | in 2024: | |
|-----|-------|----------|--|
| | cputs | | |

| Output | Indicator | Target |
|---|--|---------|
| Staff survey on the level of awareness of how to report fraud | Once a critical mass (more than 50%) of staff has attended the "Fraud staying vigilant" training | Q1 2024 |
| 'Fraud staying vigilant" training | 100% of staff having attended the course | Q4 2024 |

^{(&}lt;sup>22</sup>) <u>Communication from the Commission 'Commission Anti-Fraud Strategy Action plan - revision 2023</u> <u>COM(2023) 405 of 11 July 2023</u> -'the Communication on the 2023 revision' - and the accompanying document, <u>SWD(2023) 245</u> - 'the revised Action Plan'.

^{(&}lt;sup>23</sup>) Correction of fraud is an umbrella term, which notably refers to the recovery of amounts unduly spent and to administrative sanctions.

D. Digital transformation and information management

Objective: HERA is using innovative, trusted digital solutions for better policy-shaping, information management and administrative processes to forge a truly digitally transformed, user-focused and data-driven Commission

| Main outputs in 2024: | | |
|---|---|---------------------|
| Output | Indicator | Target |
| Digital Culture Preparation of users to operate the HERA IT platform. | All required HERA staff registered to the "train-the-Trainer" and other sessions is completing successfully the training session to operate the HERA IT platform. | Q4 2024 |
| Promotion for awareness around Cyber Security and the use of Artificial Intelligence. | 80% of HERA staff participating to the knowledge hours and info sessions on Cybersecurity and Artificial Intelligence | Throughout the year |
| Business-drivenDigitalTransformation- Seamless Digital Environment | Acceptance the first functionalities (secured survey and case management) of the HERA IT platform. | 100% Q4 2024 |
| - Green, Resilient and Secure Digital Infrastructure | Acceptance of the analysis of the future features for the HERA, including the security aspects. Uptake of ITSRM for security assessment and plans | 100% Q1 2025 N/A |
| Increase staff awareness in HERA on personal data protection rules. | Percentage of staff attending awareness raising activities | Staff: 70 % |
| Mapping of implementation of data protection rules and increasing monitoring capabilities | Number of unit inventories | 4 Unit Inventories |

| Output | Indicator | Target |
|---|--|---------------------|
| List of actions to implement the corporate principles for data governance for [the service's] key data assets (²⁴) | Percentage of implementation of the corporate principles for data governance for [the service's] key data assets | Target by 2024: 80% |
| List of actions to be implemented, as identified by the IT Security Strategy 2023-2024 that concern the DG | Number of implemented actions identified by the IT Security Strategy 2023-2024 that concerns the DG | 2 |

E. Sound environmental management

Objective: HERA takes account of the environmental impact of its day-to-day actions, taking measures to reduce the impact of the administration work, supported by their respective EMAS Correspondents or EMAS Site Coordinators.

Main outputs in 2024:

I Reducing emissions from staff and expert' business travel and reducing CO2 and other atmospheric emissions

| Output | Indicator | Target (2019 as baseline) |
|---|---|---|
| Reduced emissions from staff missions. HERA signed the relevant EC Services' Travel Pledge committing to reduce their GHG emissions from professional travel | CO ₂ emissions from DG's staff missions | 20 % reduction of the carbon footprint as established end of 2023 (for the first time in HERA). |

^{(&}lt;sup>24</sup>) For each key data asset, departments should assess if the following principles have been respected (see also this <u>practical guidance</u>):

Identify and designate the data owner and the data steward(s).

Instruct their data stewards to share the metadata of their data assets in the Commission's data catalogue and to keep them up to date.

Design and document processes for data collection/creation, acquisition, access, sharing, use, processing preservation, deletion, quality, protection, and security. Information concerning these processes should be made available to anyone interested, as long as any confidentiality restrictions are respected.

Make any necessary changes and updates to the IT systems used for storing, managing, and disseminating these data assets to implement the aforementioned requirements and processes.

II. Reducing resource use in buildings and workspace (energy) More efficient use of resources (energy):

| Output | Indicator | Target (2019 as baseline, as appropriate) | |
|--|---|--|--|
| Participation in corporate energy saving actions, by closing down DG/service's buildings during the Christmas and New Year's / summer holiday period, and/or optimisation of the temperature in EC buildings. | - end of year energy saving action - summer energy saving action | % of department's buildings participating in - end of year energy saving action - summer energy saving action [number of closed days] Footnote: Depending on the agreement with other occupants in our building L-15 (DG NEAR). | |
| III. V. Staff awareness | | | |

| Output | Indicator | Target (2019 as baseline, as appropriate) |
|---|---|--|
| Awareness actions in the framework of EMAS corporate campaigns on (for instance): - Energy and water use - Waste reduction/sorting: Waste reduction: Implementation of the EC Guidelines for sustainable meetings and events, e.g. sustainable catering, reduce/eliminate single-use plastics, gadgets/gifts | Number of awareness/participatory actions Number (or %) of participants | At least 1 100 % |